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PROFESSION

Doctor-pharma ties defended on eve of pay reporting mandate

■ Major stakeholders outline principles of physician-industry collaborations amid concern that all payments will be painted with a broad brush.

By KEVIN B. O'REILLY (HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=KOREILLY) amednews staff — Posted March 25, 2013

With the start of federally required tracking of industry payments to physicians to begin in August, some of the biggest names in medicine are staking a claim that shining a light on the financial ties between health industry companies and physicians should not discourage relationships that yield beneficial innovations in patient care.

In a statement of principles released March 11, a wide range of trade groups for pharmaceutical companies, device manufacturers, clinical research organizations and medical schools joined with physician organizations representing osteopathic doctors, neurosurgeons and other medical specialties to defend the value of research projects and other relationships among doctors and health industry companies.

"If this whole issue of physician-industry collaboration is not handled in the appropriate way, it could inhibit innovation," said Mary R. Grealy, president of the Healthcare Leadership Council, a Washington-based nonprofit group. Its members are the chief executives at major players in health care such as AstraZeneca, Ascension Health Alliance, Cleveland Clinic Foundation, Eli Lilly & Co. and Walgreen Co. The council convened a 2010 summit and subsequent meetings that led to the statement.

The coalition outlined a framework to guide interactions between industry and physicians that seeks to protect doctors' autonomy in providing care, to give patients and others access to "meaningful information" about collaborations, to use training and communication to assure compliance with professional codes of conduct, and to focus on the benefit of such interactions for patients.

"One of the reasons we're developing these principles and working with this diverse group is that, as we begin to report and go public with the exchanges of value between industry and physicians — if it's not done in a way that has some context — it might have a chilling effect on having those collaborations," Grealy said.

The Centers for Medicare & Medicaid Services issued the final rule to implement the Physician Payments Sunshine Act in February. Starting in August, pharmaceutical companies and device manufacturers must begin tracking physician payments and gifts worth as little as $10. Public disclosure of these so-called transfers of value in a searchable federal government database starts Sept. 30, 2014.

The American Medical Association was not involved in the Healthcare Leadership Council's statement of principles on physician-industry collaboration. The Association is developing tools to help doctors understand the Sunshine Act and talk with patients about their listings. Resources are available on an AMA website (link).

"Physicians' relationships with the pharmaceutical industry should be transparent and focused on benefits to patients," said AMA President Jeremy A. Lazarus, MD. "Many interactions between physicians and the pharmaceutical and medical device industries occur to advance clinical research that is essential to ensure the discovery of treatments and improve patient care. The new Physician Payments Sunshine Act is not meant to stifle these important interactions."

Disclosure's impact unclear

Experts see little certainty about the law's likely effect on research, industry-sponsored physician lectures, meals provided by drug reps and other types of interaction by pharma with doctors.

Already, about 25% of physician practices refuse to see drug reps, according to an ongoing survey of hundreds of thousands of U.S. clinics by SK&A, a prescriber-profiling firm. A majority of U.S. medical schools now prohibit all gifts and on-site meals paid for by pharmaceutical companies and device manufacturers. Yet a study in the Feb. 27 issue of the *Journal of General Internal Medicine* found that 57% of fourth-year medical students and 54% of residents got gifts such as meals.

Among practicing physicians, more than half say they are unaware that the Sunshine Act will require industry companies to report transfers of value to doctors annually. That is according to a survey of more than 1,000 physicians released in February by the health technology company MMIS. The money that drug- and device-makers spend on in-office meals will be reported publicly if the amount spent on an individual doctor exceeds $100 over a year.

DID YOU KNOW: 25% of physician practices refuse to see pharmaceutical manufacturing representatives.

In March, the nonprofit news outlet ProPublica updated its database of pharmaceutical company payments to doctors, which is drawn from disclosures by 15 drugmakers who account for nearly half of the market. Between 2009 and 2012, the companies paid nearly $2 billion to doctors for speaking, consulting, travel, meals, as educational items or gifts, and in royalties or license fees. Payments for speaking services declined, but industrywide trends were hard to determine. Pharma spending seemed to fluctuate over time with an individual company's product line, research strategy and marketing plans, said Charles Ornstein, who directs the ProPublica database project.

How physician-payment disclosure legislation may translate into clinical practice also remains opaque. Two states that enacted physician payment-disclosure legislation in 2004 — Maine and West Virginia — saw no substantial shift from brand-name drugs for two classes of medications for which there are highly substitutable generic alternatives, according to a May 28, 2012, study in *JAMA Internal Medicine*, formerly *Archives of Internal Medicine*.

Relationship already cooling

There is more evidence to indicate that, pre-Sunshine Act, doctors were interacting less with industry. Between 2004 and 2009, there was a drop in doctors' relationships with pharmaceutical companies, according to a Nov. 8, 2010, study in *JAMA Internal Medicine*. The percentage of doctors who accepted food or drinks at the office fell from 83% to 72%, while those engaged in consulting arrangements dropped from 18% to 7%.

Service on company advisory boards and speakers bureaus also fell. It is unclear whether that pattern, driven largely by changing professional norms within medicine, will continue when the first Sunshine Act reports go public, said Eric G. Campbell, PhD, the study's lead author.

"So much will depend on how it's reported and what people can tell when they look at the data," said Campbell, professor of medicine at Harvard Medical School in Boston. "There are certainly many physicians who would have no problem providing cogent, reasonable reasons why they engage in this activity. And not all of these relationships are marketing. Some are about research and developing new products or services, and we want doctors to talk with drug companies about this stuff."

Daniel Carlat, MD, said the concern that payment disclosure will discourage physician collaborations with industry in research and development is overblown.

"I doubt that we're going to see a chilling effect on those activities most important for advancing medical science," said Dr. Carlat, director of the Pew Charitable Trusts' Prescription Project. "We've had some companies disclosing payments since 2009, and we haven't seen research grinding to a halt due to that."

In the Sunshine era, he added, physicians will think twice about their interactions with drugmakers and other health industry firms. Such circumspection should be welcomed as a positive development, Dr. Carlat said.

Questions about physicians' payment listings are unlikely to come from their patients, said Robert Harbaugh, MD, treasurer of the American Assn. of Neurological Surgeons, which endorsed the Healthcare Leadership Council statement of principles. He said the likelihood of patients asking about a Sunshine listing is “vanishingly small.”

Dr. Harbaugh offered this advice for doctors in this new era of transparency: “You shouldn't be doing something that you wouldn't be proud to see on the front page of the newspaper.”

BACK TO TOP

ADDITIONAL INFORMATION

4 principles on doctor-industry interactions

Medical industry payments and gifts to physicians will be made public starting Sept. 30, 2014. A coalition of drugmakers, device manufacturers, medical centers and physician organizations has outlined the principles it believes should guide financial relationships among doctors and industry.

- **The benefit of patients:** Collaborations at any level, from the research lab to the doctor's office, must aim to benefit patients and put patients' interests first.
- **The autonomy of health care professionals:** Health care professionals and scientists must be free to independently assess multiple sources of information and treat each patient in a manner consistent with the patient's needs and best medical practice. This is vital to preserve the public's trust in the innovation process and in our health care system.
- **Transparency:** Patients, and all those involved in health care, should have reasonable access to relevant and meaningful information about how academic institutions, researchers, health care professionals and medical products companies engage in collaborative relationships. Transparency builds trust between patients and the health care professionals who serve them.
- **Accountability:** All participants across health care must be responsible for their actions. External regulation is important here, but self-regulation with recurrent training and communication is essential to this effort.

Source: “A Joint Statement on 21st Century Collaboration for Healthcare Advancement,” National Dialogue for Healthcare Innovation, March 11 (link)

BACK TO TOP

EXTERNAL LINKS

“Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests,” *Federal Register*, Feb. 8 (**link: https://www.federalregister.gov/a/2013-02572**)

American Medical Association resources on the Sunshine Act (**link: http://www.ama-assn.org/go/sunshine**)

“Changing Interactions Between Physician Trainees and the Pharmaceutical Industry: A National Survey,” *Journal of General Internal Medicine*, published online Feb. 27 (**link: http://www.ncbi.nlm.nih.gov/pubmed/23444007/**)

“Effect of Physician Payment Disclosure Laws on Prescribing,” *JAMA Internal Medicine*, formerly *Archives of Internal Medicine*, May 28, 2012 (**link: http://archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2012.1210**)

“Physician Professionalism and Changes in Physician-Industry Relationships From 2004 to 2009,” *JAMA Internal Medicine*, formerly *Archives of Internal Medicine*, Nov. 8, 2010 (**link: http://archinte.jamanetwork.com/article.aspx?doi=10.1001/archinternmed.2010.383**)

“A Joint Statement on 21st Century Collaboration for Healthcare Advancement,” National Dialogue for Healthcare Innovation, March 11 (**link: http://www.ndhi.org/resource/1363357333000/NDHI_Principles_Statement_Final**)

BACK TO TOP